"best available therapy" (Melton et al., 1988). Some have advised patients to enroll in randomized clinical trials with the covert intention of withdrawing if randomized to the "inferior arm" (Marquis and Stephens, 1989). These are not ethically acceptable behaviors and they do not necessarily reflect competent judgments (Levine, 1989).

Suppose there is a randomized clinical trial comparing therapy A with therapy B in the treatment of condition C. Doctor S believes that therapy A is superior to therapy B for condition C. Can Dr. S advise patient P with condition C to enroll in the randomized clinical trial without violating the ethical requirements of the personal care principle?

To that question I would answer "yes" if the randomized clinical trial has been justified according to the concept of clinical equipoise as constructed by Freedman (1987). "A state of clinical equipoise is consistent with a decided treatment preference on the part of the investigators. They must simply recognize that their less-favored treatment is preferred by colleagues whom they consider to be responsible and competent."

What about physicians who consider their colleagues either irresponsible or incompetent? What about physicians who feel they have special insights into the truth about therapies that are not shared within the clinical community? If their insights are based upon scientific evidence, they should present their evidence in an appropriate forum. If they are convinced that a randomized clinical trial is not justified, they should present evidence to support this belief to agencies having the authority to disapprove or terminate the randomized clinical trial.

Physicians are expected to conduct their practices and advise their patients according to standards established by and accepted within the clinical community. This community standard is designed to protect the public from deviant physicians who believe they have special insights into the truth about therapies. By definition, in a state of clinical equipoise, the community standard is that the relative merits of the therapies in such a state are not known.

Thus, a competent physician may, in many cases, offer to a patient an opportunity to consider participation in a randomized clinical trial comparing therapies A and B even though he or she believes A is superior to B without violating the personal care principle. When therapies A and B are in a state of clinical equipoise, the physician's belief regarding the superiority of A is to be distinguished from a "competent judgment."

Comment: Personal and Impersonal Care

Foster Lindley

INTRODUCTION

Doctor Royall has performed a distinctive service in canvassing the most important ethical considerations prompted by the practice of randomizing patients to different therapies in clinical trials. I agree with the thrust of his paper favoring nonrandomized clinical studies and will comment briefly on some of his arguments while adding my own. I am hoping that more reflection by investigators on why it is that chance is so important to them will make alternative procedures seem less threatening.

First, a personal note. I came upon James Ware's article "Therapies of Potentially Great Benefit: ECMO" in the November 1989 issue of this journal, by chance. I was so affected by what was said, as well as how it was said, that I could not complete it in a single sitting. If it had not been for the comments by Berry and Royall, thanks to the editorial format, I would have concluded that I simply misunderstood it. I did not realize that decisions regarding alternative statistical strategies, like decisions regarding alternative therapies, have themselves become matters of life and death. That people die in the service of abstract, controversial, statistical proofs, I cannot accept. That they die at the hands of physicians who mistakenly prefer one therapy to another, I can accept. Some will see an inconsistency there; I do not.

Foster Lindley is Professor of Philosophy, Emeritus, The University of Connecticut. His mailing address is 32 Ledgewood Drive, Storrs, Connecticut 06268.

ANY PARALLEL TRIAL IS IMPERSONAL

With the exception of the brief paragraph at the close, which I hope he will expand in his rejoinder, Royall's objection to the randomization principle is

Institute of Mathematical Statistics is collaborating with JSTOR to digitize, preserve, and extend access to *Statistical Science.* www.jstor.org